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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/579,529

03/06/2007

William G. Cance

69774(49163)

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21874 7590 12/06/2010
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BOSTON, MA 02205

EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

12/06/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/579,529 | Applicant(s) CANCE ET AL. | |
| | Examiner ANNE L. HOLLERAN | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-47 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 12-17 and 23-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-11 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The responses filed 11/02/2009 and 3/16/2010 are acknowledged.

Claims 1, and 3-47 are pending.

Claims 4, 5, 12-17, 23-47, drawn to non-elected inventions, are withdrawn from consideration.

Claim Objections

Claim 3 is objected to because it depends from a cancelled claim. Therefore, it is not further examined on the merits, and is withdrawn from consideration.

Claims 1, 6-11 and 18-22 are examined on the merits.

Claim Rejections Withdrawn:

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Hungerford (Hungerford, J.E., et al., The Journal of Cell Biology, 135(5): 1383-1390, 1996; cited in the restriction requirement) is withdrawn in view of the amendments to claim 1.

The rejection of claims 1, 2, 6-11, 18, and 21 under 35 U.S.C. 102(e) as being anticipated by Sauk (US 7,361,730; Apr., 22, 2008; effective filing date Mar. 15, 1999) is withdrawn in view of the amendments to the claims.

The rejection of claims 1-3, 6-11 and 18-20 under 35 U.S.C. 103(a) as being unpatentable over Sauk (supra) in view of Bermudes (US 6,962,696; issue Nov. 8, 2005; effective filing date 10/4/1999) is withdrawn in view of the amendment to the claims.

Claim Rejections Maintained and New Grounds of Rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-11, and 18-22 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the disclosure of the specification does not provide adequate support for the genus of agents that specifically bind focal adhesion kinase and induce apoptosis, or for compositions comprising fragments, variants or derivatives of SEQ ID NO: 3.

For a claim drawn to a genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A “representative number of species” means that the species, which are adequately described, are

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representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see Official Gazette 1241 OG 174, January 30, 2001).

Claims 6-11 and 18-22 encompass compositions comprising peptides, where the peptides may be those that are fragments, derivatives or variants of SEQ ID NO: 3.

The specification provides the teaching of SEQ ID NO: 1 or SEQ ID NO: 3, which appear to be peptides that are unrelated structurally because a search of SEQ ID NO: 1 does not provide documents teaching SEQ ID NO: 3. Therefore, there does not appear to be a correlation between the particular amino acid sequence of either SEQ ID NO: 1 or SEQ ID NO: 3 that correlates with the functions of binding to focal adhesion kinase and the induction of apoptosis. Therefore, one of skill in the art cannot use the teachings of SEQ ID NO: 1 or SEQ ID NO: 3 to envision the structures of fragments, variants or derivatives that will be peptides that bind to focal adhesion kinase and also induce apoptosis. The specification does not provide working examples of variants or fragments or a discussion of critical residues that are necessary for binding to focal adhesion kinase and the induction of apoptosis. Therefore, the specification fails to provide an adequate disclosure to support the breadth of the claimed agents or compositions.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 8-11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis-Smyth (US 6,100,071; issued Aug. 8, 2000), as evidenced by Garces et al (Garces, C.A., et al. Cancer Res. 66(3): 1446-1454, 2006).

Claims 1, 6 and 18 are drawn to agents or compositions that comprise SEQ ID NO: 3.

The term “comprise” is an open ended transitional phrase that allows the presence of other elements. SEQ ID NO: 3 is a fragment of a larger protein, VEGFR-3 or flt-4 (see alignment). Claims 8-11 recite intended uses for the claimed compositions, where the intended uses do not appear to change the scope of the claimed product.

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RESULT 2
US-08-643-839-3
; Sequence 3, Application US/08643839
; Patent No. 6100071
; GENERAL INFORMATION:
;   APPLICANT: Davis-Smyth, Terri L.
;   APPLICANT: Chen, Helen H.
;   APPLICANT: Presta, Leonard
;   APPLICANT: Ferrara, Napoleone
;   TITLE OF INVENTION: NOVEL INHIBITORS OF VASCULAR ENDOTHELIAL
;   TITLE OF INVENTION: GROWTH FACTOR ACTIVITY, THEIR USES AND PROCESSES FOR THEIR
;   TITLE OF INVENTION: PRODUCTION
;   NUMBER OF SEQUENCES: 48
;   CORRESPONDENCE ADDRESS:
;     ADDRESSEE: Flehr, Hohbach, Test, Albritton & Herbert
;     STREET: Four Embarcadero Center, Suite 3400
;     CITY: San Francisco
;     STATE: California
;     COUNTRY: United States
;     ZIP: 94111-4187
;   COMPUTER READABLE FORM:
;     MEDIUM TYPE: Floppy disk
;     COMPUTER: IBM PC compatible
;     OPERATING SYSTEM: PC-DOS/MS-DOS
;     SOFTWARE: PatentIn Release #1.0, Version #1.30
;   CURRENT APPLICATION DATA:
;     APPLICATION NUMBER: US/08/643,839
;     FILING DATE: 07-MAY-1996
;     CLASSIFICATION: 435
;   ATTORNEY/AGENT INFORMATION:
;     NAME: Dreger, Walter H.
;     REGISTRATION NUMBER: 24,190
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;      REFERENCE/DOCKET NUMBER:  A-63291/WHD
;      TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  (415) 781-1989
;      TELEFAX:    (415) 398-3249
;      TELEX:      910 277299
;      INFORMATION FOR SEQ ID NO:  3:
;      SEQUENCE CHARACTERISTICS:
;      LENGTH:     777 amino acids
;      TYPE:       amino acid
;      STRANDEDNESS: unknown
;      TOPOLOGY:   unknown
;      MOLECULE TYPE: protein
US-08-643-839-3

```

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Query Match          100.0%;  Score 90;  DB 2;  Length 777;
Best Local Similarity 100.0%;
Matches 12;  Conservative 0;  Mismatches 0;  Indels 0;  Gaps 0;

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QY      1  WHWRPWT PCKMF 12
          |||||
Db      458 WHWRPWT PCKMF 469

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Davis-Smyth teaches SEQ ID NO: 3, which is the sequence of flt-4 (VEGFR-3), and which comprises the SEQ ID NO: 3 of the instant claims. Garces teaches that VEGFR-3 binds to focal adhesion kinase (page 1449, left to right columns), which is an inherent property of the SEQ ID NO: 3 of Davis-Smyth. Davis-Smyth teaches the chimeric molecule of claim 18 because Davis-Smyth teaches VEGF receptor-immunoglobulin chimeras (see col. 17, line 30 - col. 19, line 8). Therefore, Davis-Smyth teaches the agents and compositions as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6-11 and 18-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Davis-Smyth (US 6,100,071; issued Aug. 8, 2000; *supra*) in view of Bermudes (US 6,962,696; issue Nov. 8, 2005; effective filing date 10/4/1999; *supra*).

Davis-Smyth teaches VEGFR-3 as part of a chimeric molecule, but does not teach a chimeric molecule with a targeting domain, such as an HIV TAT domain.

Bermudes teaches the use of TAT to enable internalization of polypeptides (see for example 81, line 1- column 82, line 45; see column 13, lines 1 -28). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to

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have combined the teachings of Davis-Smyth with those of Bermudes to make the claimed inventions, where the fusion partner is a protein such as HIV TAT domain. One would have been motivated by the teachings of Bermudes that TAT is useful for creating peptides that may be internalized by tumor cells for the purpose of treating cancer.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook

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Yu, can be reached on (571) 272-0839. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643